February 6, 2009

SENATE BILL No. 575

DIGEST OF SB 575 (Updated February 4, 2009 12:35 pm - DI 104)

Citations Affected: IC 5-31; IC 16-18; IC 16-42; IC 25-26; IC 35-48.

Synopsis: Tamper resistant prescription drug forms. Requires the Indiana health informatics corporation to prepare a plan for statewide electronic prescribing. Requires practitioners to use official tamper resistant prescription drug forms issued by the Indiana board of pharmacy (board) when issuing a written prescription. Prohibits a pharmacist from filling a written prescription that is issued by an Indiana practitioner if the prescription is not on an official tamper resistant prescription drug form. Requires the board to: (1) develop and issue the official tamper resistant prescription drug form; and (2) develop a prescription drug program that includes criteria to eliminate prescription drug fraud. Requires practitioners to notify the board if the forms are lost, stolen, or not received. Specifies requirements for the official tamper resistant prescription drug forms.

Effective: July 1, 2009.

Dillon

January 20, 2009, read first time and referred to Committee on Health and Provider Services.
February 5, 2009, amended, reported favorably — Do Pass; reassigned to Committee on Appropriations.

February 6, 2009

First Regular Session 116th General Assembly (2009)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2008 Regular Session of the General Assembly.

SENATE BILL No. 575

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-31-6-1, AS ADDED BY P.L.111-2007, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: Sec. 1. The corporation shall do the following:

(1) Define the vision for a statewide health information exchange system to electronically exchange health care information between entities in the health care system, including at least the following:

(A) Physicians and other health care providers.

(B) Health insurance companies and health maintenance organizations.

(C) Federal and state governmental health payers.

(D) Employers.

(E) Pharmacies and pharmacy benefit managers.

(F) Laboratories.

(G) Public health agencies.

(2) Prepare and modify, as necessary, a plan to create the statewide health information exchange system.

(3) Encourage and facilitate:

(A) the development of the statewide health information exchange system; and

(B) the ongoing operation of the statewide health information exchange system, including monitoring the performance, quality, and security of the statewide health information exchange system.

(4) Respond to changes in the market, advances in technology, and metrics related to the statewide health information exchange system by encouraging and facilitating users of the statewide health information exchange system and other interested parties in building upon, adapting, and improving the statewide health information exchange system.

(5) Evaluate, analyze, and report on Indiana's progress toward implementing the statewide health information exchange system.

(6) Promote the use of the statewide health information exchange system by doing the following:

(A) Encouraging and facilitating users of the statewide health information exchange system and other interested parties in developing and adopting standards for the statewide health information exchange system.

(B) Recommending policies and legislation that advance the development and efficient operation of the statewide health information exchange system.

(C) Educating business and health care leaders and the public regarding the existence and benefits of the statewide health information exchange system.

(7) Develop programs and initiatives to promote and advance the exchange of health information to improve the safety and quality of patient care and to reduce the waste associated with redundancy and administrative costs. The corporation shall do the following to carry out the corporation's duty under this subdivision:

(A) Cooperate with federal, state, and local governments and agencies in the coordination of programs to make the best use of Indiana's information and technology resources.

(B) Receive and expend funds, grants, gifts and contributions of money, property, labor, interest accrued from loans made by the corporation, and other things of value from public and private sources, including grants from agencies and instrumentalities of the state and federal government. The corporation:

(i) may accept federal grants to carry out the corporation's purposes;

(ii) shall administer these grants in accordance with the terms of the grants; and

(iii) may contract with public or private organizations to carry out the purposes for which the grants were made.

(8) Review efforts in other states concerning health information exchange.

(9) Encourage and facilitate the development of health information exchange for those areas of Indiana where health care referral patterns cross state boundaries.

(10) Encourage and endorse interoperability standards.

(11) Prepare a plan to implement statewide electronic prescribing.

SECTION 2. IC 16-18-2-256.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 256.5. "Official tamper resistant prescription form", for purposes of IC 16-42-22, has the meaning set forth in IC 16-42-22-5.7(b).**

SECTION 3. IC 16-42-22-4.5, AS AMENDED BY P.L.157-2006, SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: Sec. 4.5. As used in this chapter, "practitioner" means any of the following:

(1) A licensed physician.

(2) A dentist licensed to practice dentistry in Indiana.

(3) A podiatrist licensed to practice podiatric medicine in Indiana.

(4) An optometrist who is:

(A) licensed to practice optometry in Indiana; and

(B) certified under IC 25-24-3.

(5) An advanced practice nurse licensed and granted the authority to prescribe legend drugs under IC 25-23.

(6) A physician assistant who has the authority to prescribe legend drugs as delegated by a supervising physician under IC 25-27.5-5.

SECTION 4. IC 16-18-2-292 IS AMENDED TO READ AS FOLLOWS: Sec. 292. "Prescription", for purposes of IC 16-42-19 **and IC 16-42-22,** has the meaning set forth in IC 16-42-19-7.

SECTION 5. IC 16-42-22-5.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 5.7. (a) This section does not apply to the following:**

(1) A prescription that is generated within a licensed health

care facility if:

(A) the prescription drug is dispensed internally to a patient receiving treatment at the facility; and

(B) the patient is never in possession of the prescription.

(2) A prescription written by a practitioner who is not licensed in Indiana.

(b) As used in this section, "official tamper resistant prescription drug form" means a prescription drug form that meets the following conditions:

(1) Is issued by the Indiana board of pharmacy or a contractor for the board of pharmacy.

(2) Prevents the erasure or modification of written instructions.

(3) Prevents counterfeit forms.

(4) Supports the capability of automated validation through a pharmacy claims processing system.

(c) As used in this section, "SAS 70 audit" refers to the Statement on Auditing Standards No. 70, an internationally recognized auditing standard developed by the American Institute of Certified Public Accountants.

(d) Each written prescription issued by a practitioner must be written on an official tamper resistant prescription drug form.

(e) Except as provided in subsection (f), a pharmacist may not fill a written prescription from a practitioner licensed in Indiana unless the prescription is issued on an official tamper resistant prescription drug form.

(f) A pharmacist may provide emergency supplies of a prescription as allowed by law.

(g) The Indiana board of pharmacy shall develop the following:

(1) A prescription drug program that includes criteria to eliminate or significantly reduce prescription fraud.

(2) A standard format for the official tamper resistant prescription drug form, which must include the following:

(A) A counterfeit protection bar code with human readable representation of the data in the bar code.

(B) A thermochromic mark on the front and the back of the prescription that:

(i) is at least one-fourth (1/4) of one (1) inch in height and width; and

(ii) changes from blue to clear when exposed to heat.

(h) The Indiana board of pharmacy shall provide a practitioner with official tamper resistant prescription drug forms at no charge

to the practitioner. The official tamper resistant prescription drug form may only be used by the practitioner to whom it was issued, and the forms may not be transferred.

(i) A practitioner shall immediately inform the Indiana board of pharmacy of the following:

(1) The loss, destruction, theft, or unauthorized use of an official tamper resistant prescription drug form issued to the practitioner.

(2) The failure to receive ordered official tamper resistant prescription drug forms within a reasonable time.

The board shall take appropriate action, including notifying the office of the attorney general.

(j) The Indiana board of pharmacy may contract with a supplier to implement and manage the prescription drug program. The supplier must:

(1) have been audited by a third party auditor using the SAS 70 audit or an equivalent audit for at least the three (3) previous years; and

(2) be audited by a third party auditor using the SAS 70 audit or an equivalent audit throughout the duration of the contract;

in order to be considered to implement and manage the program.

(k) The Indiana board of pharmacy may adopt rules under IC 4-22-2 necessary to implement this section.

SECTION 6. IC 25-26-13-4, AS AMENDED BY P.L.204-2005, SECTION 15, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: Sec. 4. (a) The board may:

(1) promulgate rules and regulations under IC 4-22-2 for implementing and enforcing this chapter;

(2) establish requirements and tests to determine the moral, physical, intellectual, educational, scientific, technical, and professional qualifications for applicants for pharmacists' licenses;

(3) refuse to issue, deny, suspend, or revoke a license or permit or place on probation or fine any licensee or permittee under this chapter;

(4) regulate the sale of drugs and devices in the state of Indiana;

(5) impound, embargo, confiscate, or otherwise prevent from disposition any drugs, medicines, chemicals, poisons, or devices which by inspection are deemed unfit for use or would be dangerous to the health and welfare of the citizens of the state of Indiana; the board shall follow those embargo procedures found

in IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse to permit or otherwise prevent members of the board or their representatives from entering such places and making such inspections;

(6) prescribe minimum standards with respect to physical characteristics of pharmacies, as may be necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public;

(7) subject to IC 25-1-7, investigate complaints, subpoena witnesses, schedule and conduct hearings on behalf of the public interest on any matter under the jurisdiction of the board;

(8) prescribe the time, place, method, manner, scope, and subjects of licensing examinations which shall be given at least twice annually; and

(9) perform such other duties and functions and exercise such other powers as may be necessary to implement and enforce this chapter.

(b) The board shall adopt rules under IC 4-22-2 for the following:

(1) Establishing standards for the competent practice of pharmacy.

(2) Establishing the standards for a pharmacist to counsel individuals regarding the proper use of drugs.

(3) Establishing standards and procedures before January 1, 2006, to ensure that a pharmacist:

(A) has entered into a contract that accepts the return of expired drugs with; or

(B) is subject to a policy that accepts the return of expired drugs of;

a wholesaler, manufacturer, or agent of a wholesaler or manufacturer concerning the return by the pharmacist to the wholesaler, the manufacturer, or the agent of expired legend drugs or controlled drugs. In determining the standards and procedures, the board may not interfere with negotiated terms related to cost, expenses, or reimbursement charges contained in contracts between parties, but may consider what is a reasonable quantity of a drug to be purchased by a pharmacy. The standards and procedures do not apply to vaccines that prevent influenza, medicine used for the treatment of malignant hyperthermia, and other drugs determined by the board to not be subject to a return policy. An agent of a wholesaler or manufacturer must be appointed in writing and have policies, personnel, and facilities to handle properly returns of expired legend drugs and controlled

substances.

(c) The board may grant or deny a temporary variance to a rule it has adopted if:

(1) the board has adopted rules which set forth the procedures and standards governing the grant or denial of a temporary variance; and

(2) the board sets forth in writing the reasons for a grant or denial of a temporary variance.

(d) The board shall adopt rules and procedures, in consultation with the medical licensing board, concerning the electronic transmission of prescriptions. The rules adopted under this subsection must address the following:

(1) Privacy protection for the practitioner and the practitioner's patient.

(2) Security of the electronic transmission.

(3) A process for approving electronic data intermediaries for the electronic transmission of prescriptions.

(4) Use of a practitioner's United States Drug Enforcement Agency registration number.

(5) Protection of the practitioner from identity theft or fraudulent use of the practitioner's prescribing authority.

(e) The board shall develop:

(1) a prescription drug program that includes the establishment of criteria to eliminate or significantly reduce prescription fraud; and

(2) a standard format for the official tamper resistant prescription drug form;

as specified in IC 16-42-22-5.7.

SECTION 7. IC 35-48-7-8.1, AS ADDED BY P.L.65-2006, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: Sec. 8.1. (a) This section applies after June 30, 2007.

(b) The advisory committee shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the advisory committee under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the INSPECT program the following information:

(A) The controlled substance recipient's name.

(B) The controlled substance recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.

(C) The controlled substance recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(K) The official tamper resistant prescription drug form bar code data, as described in IC 16-42-22-5.7.

~~(K)~~ **(L)** Other data required by the advisory committee.

(2) The information required to be transmitted under this section must be transmitted not more than seven (7) days after the date on which a controlled substance is dispensed.

(3) A dispenser shall transmit the information required under this section by:

(A) uploading to the INSPECT web site;

(B) a computer diskette; or

(C) a CD-ROM disk;

that meets specifications prescribed by the advisory committee.

(4) The advisory committee may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the advisory committee may not apply such a requirement to prescriptions filled at a pharmacy with a Type II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The committee may not require multiple copy prescription forms ~~and serially numbered prescription forms~~ for any prescriptions written. The advisory committee may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be jointly approved by the committee and by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 575, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 4, line 17, after "(c)" insert "**As used in this section, "SAS 70 audit" refers to the Statement on Auditing Standards No. 70, an internationally recognized auditing standard developed by the American Institute of Certified Public Accountants.**

(d)".

Page 4, line 19, delete "(d) A" and insert "**(e) Except as provided in subsection (f), a**".

Page 4, line 22, delete "(e)" and insert "**(f) A pharmacist may provide emergency supplies of a prescription as allowed by law.**

(g)".

Page 4, line 28, delete "date" and insert "**data**".

Page 4, line 34, delete "(f)" and insert "**(h)**".

Page 4, line 39, delete "(g)" and insert "**(i)**".

Page 5, line 6, delete "(h)" and insert "**(j)**".

Page 5, line 9, after "auditor" insert "**using the SAS 70 audit or an equivalent audit**".

Page 5, line 11, after "auditor" insert "**using the SAS 70 audit or an equivalent audit**".

Page 5, line 14, delete "(i)" and insert "**(k)**".

Page 7, after line 19, begin a new paragraph and insert:

"SECTION 7. IC 35-48-7-8.1, AS ADDED BY P.L.65-2006, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: Sec. 8.1. (a) This section applies after June 30, 2007.

(b) The advisory committee shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the advisory committee under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the INSPECT program the following information:

(A) The controlled substance recipient's name.

(B) The controlled substance recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.

(C) The controlled substance recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(K) The official tamper resistant prescription drug form bar code data, as described in IC 16-42-22-5.7.

~~(K)~~ **(L)** Other data required by the advisory committee.

(2) The information required to be transmitted under this section must be transmitted not more than seven (7) days after the date on which a controlled substance is dispensed.

(3) A dispenser shall transmit the information required under this section by:

(A) uploading to the INSPECT web site;

(B) a computer diskette; or

(C) a CD-ROM disk;

that meets specifications prescribed by the advisory committee.

(4) The advisory committee may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the advisory committee may not apply such a requirement to prescriptions filled at a pharmacy with a Type II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The committee may not require multiple copy prescription forms ~~and serially numbered prescription forms~~ for any prescriptions written. The advisory committee may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be jointly approved by the committee and by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.".

Renumber all SECTIONS consecutively.

and when so amended that said bill be reassigned to the Senate Committee on Appropriations.

(Reference is to SB 575 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 9, Nays 0.